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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,236	09/17/2003	John H. Stevens	15302ZYXWAZ (HRT-176)	6287
7590 05/25/2006 Scully, Scott, Murpht & Presser 400 Garden City Plaza Ste. 300 Garden City, NY 11530			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/665,236

Applicant(s)

STEVENS ET AL.

Examiner

DAVID J. ISABELLA

Art Unit

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

***Response to Amendment***

Applicant's arguments concerning the status of claims 40-42 are correct. These claims were inadvertently not included in a rejection on the merits and, therefore, the finality of that action is withdrawn.

***Status of the Claims***

Currently, claims 1-21 have been cancelled and new claims 22—42 are pending

***Status of the Terminal Disclaimer***

The Terminal disclaimer as filed on 11/20/2004 has been approved for entry.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Jarvik [5738626].

The method of reshaping a patient's heart comprising reducing the dimension of the left ventricle by a predetermined amount is fully disclosed by Jarvik. While Jarvik fails to specifically set forth the steps how the gauging of the size of the left ventricle is done, the step is performed and used for determining the amount by which the left ventricle should be reduced. Whether the gauging is in the form of a mental, visual, imaging or physical step, it is clear that Jarvik fulfilled the steps as claimed by applicant in the reduction of the size of the patient's left ventricle. Moreover, Jarvik indicated that ventricular aneurysmectomy has been used over the past several decades. Clearly the practice for reducing the size of the ventricular chamber has been performed in the art well before that of applicant's method.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derek Gordon 1997 (Publication Time Publication; "Too Big a Heart") in view of Berman et al (5613302) and/or either of Kress (4624671) or Hinnenkamp et al (5814098).

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Applicant argues that the publication dated 1997 is after the date of applicant's earliest date however, examiner maintains that the 1997 date is not the earliest date as the Batista procedure was utilized by others before the 1997 date and as early as 1994. Moreover, Dr. Batista ventriculectomy method was disclosed and known to others before 1997. Examiner contends that the mental steps required to reduce the dimension of the ventricle would inherently encompass the broad step of "gauging the current size of the heart diameter and estimating the desired size after reduction is performed by the surgeon.

The method of reshaping a patient's heart comprising reducing the dimension of the left ventricle by a predetermined amount is fully disclosed by Batista, et al. While Batista fails to specifically set forth the steps of gauging the size of the left ventricle and determining the amount by which the left ventricle should be reduced from the gauging, such steps are inherent and essential to performing the reshaping of the ventricle chamber. Whether the gauging is in the form of a mental, visual, imaging or physical step, it is clear that Batista, et al fulfilled the steps as claimed by applicant in the reduction of the size of the patient's left ventricle.

Dr. Batista and the Batista procedure was developed in the early 1980s. The procedure involved a partial left ventriculectomy in which an enlarged heart muscle wall is removed and the ratio heart diameter to mass could be returned to a near normal level. The determination of muscle mass to heart size was found to be based on the law of La Place:  $mass = 4 \times radius^3$ . This relationship as described by Batista, inherently requires the step of gauging the size of the left ventricle so that determination of the

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amount of tissue that should be removed which will allow the heart to return to near normal level. Moreover, the article states that this procedure was performed on a Brazilian patient back in 1994. Clearly, the procedure for reshaping a patient's heart comprising: gauging the size of the left ventricle; determining the amount by which the left ventricle should be reduced from the gauging of its size; and reducing the dimension of the left ventricle in accordance with the determined amount is fully met by what is widely known as the "Batista procedure". The size of the heart according to Batista is proportional to the circumference (ie determined radius of the heart). These dimensions may be obtained by well known circumferential measurements or volumetric determinations known in any art for determining dimensional parameters of a three dimensional structure including body organs. Each of Kress, Hinnenkamps, et al and Berman et al teach methods for determining size of three dimensional tissues. While the prior art is not specific to the organ of the heart, applicant's claims is not specific to any particular features of the tool used to obtain the measurements used in determining the dimension of the ventricle. Applicant's method steps broadly defines the gauging steps as using an adjustable band or a expansible member. The art clearly establishes that the broad concepts for gauging dimensional characteristics of a three dimensional object with the use of a band length and/or an expansible member is well known in any art. Lacking any specific features of the tools to accomplish the measurements, examiner contends to use either types of measuring devices, tape or expansion type, to determine the physical size of the affected heart tissue would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

Claims 23,38-42, see band of Berman et al and reduction method of Gordon/Batista as illustrated in the figure on page 5 of Gordon.

Claims 24-26,31,32,33 see expansion member of Kress and Hinnenkamps et al.

Claims 27-30,34-37, see figure on page 5 of Gordon and reduction method as taught by Bastita.

Claims 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarvik [5738626] in view of Berman et al (5613302) and/or either of Kress (4624671) or Hinnenkamp et al (5814098).

Each of Kress, Hinnenkamps, et al and Berman et al teach methods for determining size of three dimensional tissues. While the prior art is not specific to the organ of the heart, applicant's claims is not specific to any particular features of the tool used to obtain the measurements used in determining the dimension of the ventricle. Applicant's method steps broadly defines the gauging steps as using an adjustable band or a expansible member. The art clearly establishes that the broad concepts for gauging dimensional characteristics of a three dimensional object with the use of a band length and/or an expansible member is well known in any art. Lacking any specific features of the tools to accomplish the measurements, examiner contends to use either types of measuring devices, tape or expansion type, to determine the physical size of the affected heart tissue would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

***Response to Arguments***

Applicant's arguments filed 1/9/2006 have been fully considered but they are not persuasive.

On page 5 of the article, the figure illustrates the reduction to the heart tissue occurring primarily in the ventricular region of the heart. The gauging of the heart includes the ventricle and the step of determining the amount of reduction pertains to the ventricle and the reducing is in accordance with the determined amount with respect to the ventricle. Examiner agrees with applicant that Gordon and Batista is silent as to the means for measuring or determining of the enlarged heart tissue. However, examiner relied on each of Kress, Hinnenkamps, et al and Berman et al teach methods for determining size of three dimensional tissues. While the prior art is not specific to the organ of the heart, applicant's claims is not specific to any particular features of the tool used to obtain the measurements used in determining the dimension of the ventricle. Applicant's method steps broadly defines the gauging steps as using an adjustable band or a expansible member. The art clearly establishes that the broad concepts for gauging dimensional characteristics of a three dimensional object with the use of a band length and/or an expansible member is well known in any art. If not inherent in Gordon or Batista, any known method for determining dimensional parameters of tissue as suggested by each of Kress, Hinnenkamps, et al and Berman et al would have been obvious to one with ordinary skill in any art. Lacking any specific features of the tools to accomplish the measurements, examiner contends to use either



types of measuring devices, tape or expansion type, to determine the physical size of the affected heart tissue would have been obvious to one with ordinary skill in the art at the time of the invention thereof.

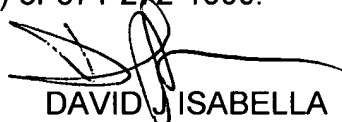
Applicant argues that neither Gordon or Batista contemplates the equivalent size or volume of the heart to the determination of the specific chamber, i.e. left ventricle. While Gordon and Batista may appear to be silent to the gauging of the ventricle, it is clear from each, that the critical volume, i.e. the major chamber that plays the critical role to adequate blood flow is the left ventricle. Since the figure shows the cutting and reduction of the left ventricle, examiner maintains that the reduction to the volume of the chamber remains the primary focus of the prior art and not simply the overall size of the heart as argued by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
5/22/2006